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Gary K. Michelson
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THREADED FRUSTO-CONICAL INTERBODY SPINAL FUSION IMPLANTS
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EXHIBIT E

APPLICATION FOR LETTERS PATENT

BY

GARY KARLIN MICHELSON, M.D.

FOR

IMPROVED FRUSTO-CONICAL INTERBODY

SPINAL FUSION IMPLANTS

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BACKGROUND OF THE INVENTION

Related Applications

This application is a continuation in part of copending United States application Serial No. 08/396,414 filed on February 27, 1995 which is a continuation-in-part of United States application Serial No. 08/074,781 filed on June 10, 1993, which is a continuation in part of United States application Serial No. 07/698,674 filed on May 10, 1991 which is a divisional of application Serial No. 07/205,935 filed on June 13, 1988, now United States Patent No. 5,015,247 all of which are incorporated herein by reference.

This application is also a continuation-in-part of United States application Serial No. 08/390,131 entitled Interbody Spinal Fusion Implants filed on February 17, 1995.

Field of the Invention

The present invention relates generally to interbody spinal fusion implants, and in particular to spinal fusion implants configured to restore and maintain two adjacent vertebrae of the spine in anatomical lordosis.

Description of The Related Art

Interbody spinal fusion refers to the method of achieving bony bridging between adjacent vertebrae through the disc space, the space between adjacent vertebrae normally occupied by a spinal disc. Numerous implants to facilitate such a fusion have been described by Cloward, Brantigan, Michelson, and others, and are known to those skilled in the art. Generally, cylindrical implants offer the advantage of conforming to an easily prepared recipient bore spanning the disc space and penetrating into each of the adjacent vertebrae. Such a bore may be created by use of a drill. It is an anatomical fact that both the cervical spine and the lumbar spine are normally lordotic, that is convex forward. Such alignment is important to the proper functioning of the spine. Commonly, those conditions which require treatment by spinal fusion are associated with a loss of lordosis.

Michelson in U.S. Patent Application Serial No. 08/396,414, entitled APPARATUS AND METHOD OF INSERTING SPINAL IMPLANTS teaches a method for restoring the anatomical lordosis of the spine while performing the interbody fusion procedure.

[REDACTED]

Therefore, there exists a need for spinal fusion implants and instrumentation that permits for the uniform depth of bone removal from each of the adjacent vertebrae while restoring anatomical lordosis.

SUMMARY OF THE INVENTION

The present invention is directed to a variety of interbody spinal fusion implants having at least a partially frusto-conical configuration and the instrumentation and methods by which the implants of the present invention can be utilized to achieve a desired anatomical lordosis of the spine.

In the preferred embodiment, the spinal fusion implants of the present invention have a body that is partially or fully frusto-conical in shape with an insertion end and a trailing end. The spinal fusion implants of the present invention may be further modified so that while the upper and lower surfaces are portions of a cone, at least one side portion may be truncated to form a planar surface that is parallel to the longitudinal axis of the implant to form straight walls. These implants may have a more tapered aspect at the small end of the cone to facilitate insertion. The spinal fusion implants of the present invention may be relatively solid or hollow and may have surface roughenings to promote bone ingrowth and stability. The spinal fusion implants of the present invention may have wells extending into the material of the implant from the surface for the purpose of holding fusion promoting materials and to provide for areas of bone ingrowth fixation. These wells, or holes may pass, either into or through the implant. The spinal

fusion implants of the present invention may have a hollow central chamber which may be in communication through various openings to the surface of the implant and such chamber may be capable of being closed with a cap or similar means. Still further, a variety of surface irregularities may be employed to increase implant stability and implant surface area, and/or for the purpose of advancing the spinal fusion implant into the fusion site. The exterior of the spinal fusion implant of the present invention may have wholly or in part, a rough finish, knurling, forward facing ratchetings, threads or other surface irregularities sufficient to achieve the purpose described. The spinal fusion implants of the present invention may be made of a mesh-like material, porous material, or any metal, plastic, ceramic or combination sufficient for the intended purpose. Such implants may be loaded with, composed of, or treated with materials to make them bioactive to the fusion process, and may be wholly or in part bioabsorbable.

The spinal fusion implants of the present invention offer significant advantages over the prior art implants:

1. Because the spinal fusion implants of the present invention are at least partially frusto-conical in shape and taper from the leading edge to the trailing edge, they are easy to introduce and easy to fully insert into the spinal segment to be fused.

2. As the spinal fusion implants of the present invention are generally implanted from the anterior to posterior aspect of the spine, the shape of the implants are consistent with the shape of the disc, which the implants at least in part replace. That is the front of the disc is normally taller than the back of the disc, which allows for normal lordosis. The implants of the present invention are similarly taller anteriorly than they are posteriorly.

3. The spinal fusion implants of the present invention allow for a minimal and uniform removal of bone from the vertebrae adjacent the disc space while still providing for an interbody

fusion in lordosis.

4. The spinal fusion implants of the present invention conform to a geometric shape, which shape is readily producible at the site of fusion, to receive said spinal fusion implants.

The spinal fusion implants of the present invention can be made of any material appropriate for human implantation and having the mechanical properties sufficient to be utilized for the intended purpose of spinal fusion, including various metals such as cobalt chrome, stainless steel or titanium including its alloys, various plastics including those which are bio-absorbable, and various ceramics. Further, the spinal fusion implants of the present invention may comprise, wholly or in part, materials capable of directly participating in the spinal fusion process, or coated with chemical substances such as bone morphogenic proteins for the purpose of stimulating fusion activity. The implants of the present invention may be wholly or in part bioabsorbable.

OBJECTS OF THE PRESENT INVENTION

It is an object of the present invention to provide a spinal implant that is easily inserted into the spine, having a tapered leading end;

It is another object of the present invention to provide a spinal implant that tapers in height from one end to the other consistent with the taper of a normal spinal disc;

It is yet another object of the present invention to provide a spinal implant that is capable of maintaining anatomic alignment and lordosis of two adjacent vertebrae during the spinal fusion process;

It is still another object of the present invention to provide a spinal implant that is self stabilizing within the spine;

It is yet another object of the present invention to provide a spinal implant that is capable of providing stability

between adjacent vertebrae when inserted;

It is still another object of the present invention to provide a spinal implant that is capable of participating in the fusion process by containing, being composed of, or being treated with fusion promoting substances;

It is further another object of the present invention to provide a spinal implant that is capable of spacing apart and supporting adjacent vertebrae during the spinal fusion process;

It is still further another object of the present invention to provide a spinal implant that is consistent in use with the preservation of a uniform thickness of the subchondral vertebral bone; and

It is another object of the present invention to provide a spinal implant the shape of which conforms to an easily produced complementary bore at the fusion site.

These and other objects of the present invention will become apparent from a review of the accompanying drawings and the detailed description of the drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a side elevational view of the spinal fusion implant of the present invention having a body that is frusto-conical with a substantially cylindrical external thread.

Figure 1A is an enlarged fragmentary view along line 1A of Figure 1 illustrating the surface configuration of the implant of Figure 1.

Figure 2 is a side elevational view of an alternative embodiment of the spinal fusion implant of the present invention having a body and an external thread that are both frusto-conical.

Figure 3 is as cross sectional view along line 3--3 of the implant of Figure 2.

Figure 4 is a side elevational view of an alternative embodiment of the spinal fusion implant of the present invention having a frusto-conical body and a surface configuration comprising ratchetings for engaging bone, with surface blasting, wells, and

channels for bone ingrowth.

Figure 5 is a cross sectional view along line 5--5 of the implant of Figure 4 illustrating the channels and wells of the implant of the present invention.

Figure 6 is a cross sectional view along line 6--6 of the implant of Figure 4 illustrating the channels and walls of the implant of the present invention.

Figure 7 is a side elevational view of an alternative embodiment of the spinal fusion implant of the present invention having a body that is made out of a fibrous metal mesh that is frusto-conical with one side that is truncated shown next to an identical second implant illustrated in hidden line.

Figure 8 is sectional view along line 8--8 of the implants of Figure 7.

Figure 9A is an enlarged fragmentary view along line 9 of Figure 7 illustrating the surface configuration of the implant of Figure 7.

Figure 9B is an enlarged fragmentary view along line 9 of Figure 7 illustrating the surface configuration of the implant of the present invention made of a cancellous material.

Figure 10 is a side elevational view in partial cut-away of an alternative embodiment of the spinal fusion implant of the present invention having a body that is frusto-conical and a surface configuration comprising a plurality of spaced apart posts.

Figure 11 is an enlarged fragmentary sectional view along lines 11--11 of Figure 10 illustrating the surface configuration of the implant of Figure 11.

Figure 12 is a side elevational view of a segment of the spinal column partially in lordosis having a first drill and a second drill for boring a hole across the disc space and into the adjacent vertebrae with the method of the present invention.

DETAILED DESCRIPTION OF THE DRAWINGS

Referring to Figure 1, a side elevational view of the spinal fusion implant of the present invention generally referred to by numeral 20 is shown. The implant 20 has a body 22 that is

frusto-conical in shape such that the body 22 has a diameter (root diameter) that is frusto-conical in shape. The body 22 has an insertion end 24 and a trailing end 26. In the preferred embodiment, the body 22 of the implant 20 has a maximum diameter at a point nearest to the trailing end 26 and a minimum diameter at a point nearest to the insertion end 24.

The implant 20 has an external thread 28 that is a substantially even cylinder, such that the external diameter of the threads (major diameter) has a substantially even cylindrical configuration. While the major diameter of the implant 20 is substantially cylindrical in shape, the external thread 28 may be modified at the leading edge by having initially a reduced thread height to facilitate insertion of the implant 20 and may also be modified to make the external thread 28 self tapping. In the preferred embodiment, the external thread 28 has a first thread 30 of a lesser height than the remainder of the external thread to facilitate insertion of the implant 20. The second thread 32 has a greater height than the first thread 30, but is still shorter than the remainder of the external thread 28 which is thereafter of constant diameter.

The frusto-conical configuration of the body 22 allows for the creating and maintaining of the adjacent vertebrae of the spine in the appropriate angular relationship to each other in order to preserve and/or restore the normal anatomic lordosis of the spine. The external thread 28 of the implant 20 is configured in a substantially cylindrical shape in order to engage the bone of the adjacent vertebrae in a position that counters the forces which tend to urge the implant 20 from between the adjacent vertebrae in the direction opposite to which the implant 20 was implanted.

The implant 20 has a recessed slot 34 at its trailing end 26 for receiving and engaging insertion instrumentation for inserting the implant 20. The recessed slot 34 has a threaded opening 36 for threadably attaching the implant 20 to the insertion instrumentation.

Referring to Figure 1A, the implant 20 has an outer surface 38 that is roughened and porous to present an irregular

surface to the bone to promote bone ingrowth. The outer surface 38 is also able to hold fusion promoting materials and provides for an increased surface area to engage in the fusion process and to provide further stability. It is appreciated that the outer surface 38 may have any other surface irregularity to promote bone